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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,611	12/15/2005	Timo Flessner	LeA 36 225	6716
35969 Barbara A. Shir	7590 10/20/200 nei	EXAMINER		
Director, Patents & Licensing			CHANDRAKUMAR, NIZAL S	
	Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor		ART UNIT	PAPER NUMBER
Tarrytown, NY 10591			1625	
			MAIL DATE	DELIVERY MODE
			10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Symmetry	10/522,611	FLESSNER ET AL.				
Office Action Summary	Examiner	Art Unit				
	NIZAL S. CHANDRAKUMAR	1625				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>09 Se</u>	entember 2008					
	· · · · · · · · · · · · · · · · · · ·					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
.—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under <i>Ex parte Quayre</i> , 1933 C.D. 11, 403 C.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-8</u> is/are pending in the application.	☑ Claim(s) <u>1-8</u> is/are pending in the application.					
4a) Of the above claim(s) 13-16 is/are withdraw	4a) Of the above claim(s) <u>13-16</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.	· · · · · · · · · · · · · · · · · · ·					
Claim(s) <u>1-8</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or						
Application Papers						
9) The specification is objected to by the Examine	r					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119	animon ricio ano alacinos cinco	7 total of 10 11 17 10 102.				
<u>. </u>	muiamitumdan 25 H.C.C. \$ 110/a)	(d) a. (f)				
2) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
·— <u> </u>	a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.					
<u> </u>						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) A) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date						
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08)	ite atent Application					
Paper No(s)/Mail Date 6) Other:						

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DETAILED ACTION

Applicants response filed 09/09/2008 is acknowledged.

Response to Applicants Remarks:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Previously presented rejection of claims 1-8 under second paragraph of 35 U.S.C. 112 with regards to solvates is maintained for reasons of record.

Applicants argue that the specification describes solvates.

The rejection is not with respect to the definition of solvates rather the rejection pertains to the albescence of disclosure of the chemical composition of the solvated compounds being claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previously presented rejection of claims 1-8 under first paragraph of 35 U.S.C. 112 is maintained.

Applicant's amendments overcome part of the rejection. Applicant's arguments with respect to solvates are not persuasive and as such the rejection is maintained for

reasons of record. Applicants state that the Examiner has not provided a concrete basis to doubt the formation of solvates.

Applicants have shown the chemical composition of 22 compounds whose compositions, as shown structurally, relate to the formation of HCl salt without any solvate present. For instance, in Example 22, the compound was obtained as hydrochloric acid salt. The preparation (described as 'reaction' in applicants' remarks page 16, line 5 from the bottom) of this salt did not result in a methanol solvate or ether solvate though both these solvents were used in the 'reaction'. This is evidenced by absence of signals corresponding to CH3 and CH3CH2 of the methanol and ether solvent adducts in the NMR spectra reported for the compound of Example 22 (see page 68 of the specification).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/D. Margaret Seaman/ Primary Examiner, Art Unit 1625